**NOT FOR PUBLICATION**

**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

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| **JANSSEN PHARMACEUTICALS, INC.,**<br><br>**Plaintiffs,**<br><br>**v.**<br><br>**PHARMASCIENCE, INC., *et al*.,**<br><br>**Defendants.** | **Civil Action No. 19-21590 (CCC)**<br><br>**MEMORANDUM OPINION & ORDER** |

**FALK, U.S.M.J.**

This Hatch-Waxman patent infringement case arises out of Pharmascience's filing of an Abbreviated New Drug Application with the United States Food and Drug Administration seeking approval to market a generic version of Janssen's Invega Sustenna® brand paliperidone-based, extended release product. Janssen contends that Pharmascience's proposed product infringes U.S. Patent No. 9,439,906 ("the '906 patent"). Before the Court is Pharmascience's letter motion seeking to amend its invalidity contentions. The application is opposed. No argument is needed. *See* Fed. R. Civ. P. 78(b).

The parties are aware of the case's background. Relevant here, the '906 patent was the subject of a recent trial between Janssen and Teva before the Honorable Claire C. Cecchi, U.S.D.J. *See Janssen v. Teva*, No. 18-734. Pharmascience contends that the trial "revealed new information relating to the patent-in-suit" which gives rise to its request to amend its invalidity contentions. Janssen counters that nothing at the trial gives rise to Pharmascience's request; that the supposedly new invalidity theories are untimely; and that any amendment would be prejudicial.

**Legal Standard**

"The Local Patent Rules exist to further the goal of full, timely discovery and provide all parties with adequate notice and information with which to litigate their case." *King Pharm., Inc. v. Sandoz*, 2010 WL 2015258, at *4 (D.N.J. May 20, 2010). The Patent Rules "are designed to require the parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed."

*Celgene Corp. v. Natco Pharma Ltd.*, 2015 WL 4138982, at *4 (D.N.J. July 9, 2015). Nevertheless, the Patent Rules are not "a straightjacket into which litigants are locked from the moment their contentions are served . . . [a] modest degree of flexibility exists, at least near the outset." *Astrazeneca AB v. Dr. Reddy's Labs, Inc*., 2013 WL 1145359 (D.N.J. Mar. 18, 2013).

Local Patent Rule 3.7 governs requests to amend contentions. The Rule allows for amendments "only by order of the Court upon a timely application and showing of good cause." *Id*. Good cause "considers first whether the moving party was diligent in amending its contentions and then whether the non-moving party would suffer prejudice if the motion to amend were granted." *Astrazeneca*, 2013 WL 1145359, at *3.

Rule 3.7 provides a "non-exhaustive" list of examples that may, absent undue prejudice to the adverse party, support a finding of good cause: "(a) a claim construction by the Court different from that proposed by the party seeking amendment; (b) recent discovery of material prior art despite earlier diligent searches; (c) recent discovery of nonpublic information about the Accused Instrumentality which was not discovered, despite diligent efforts, before the service of Infringement contentions; (d) disclosure of an infringement contention by a Hatch-Waxman Act party asserting infringement . . . that requires response by the adverse party because it was not previously presented or reasonably anticipated . . . ." *Id*.

Courts have also considered the following in determining whether good cause exists: reason for the delay; importance of the information to be excluded; the danger of unfair prejudice; and the availability of a continuance and the potential impact of a delay on judicial proceedings. *See, e.g.*, *Int'l Development, LLC v. Simon Nicholas Richmond and Adventive Ideas*, *LLC*, 2010 WL 3946714, at *3 (D.N.J. Oct. 4, 2010).

In sum, amendment will be permitted when there is "(1) a timely application, (2) there is a showing of good cause, and (3) the adverse party does not suffer undue prejudice." *Celgene Corp.*, 2015 WL 4138982, at *4.

**Decision**

The Court is satisfied that good cause has been shown for the proposed amendments, and that none of the amendments will cause undue prejudice to Janssen. As such, the motion is **GRANTED**.

**i. Timeliness and Good Cause**

Pharmascience's proposed amendments are focused on what they claim are deficiencies of the claims under 35 U.S.C. § 112. All of these deficiencies allegedly became apparent to Pharmascience by reviewing the transcripts from the *Teva* trial. In

particular, it contends that the trial transcripts: (1) "raised enablement and written description issues as [] witnesses tried to improperly limit the claims . . ."; (2) "showed that two terms in the asserted claims were both indefinite and not enabled by the patent specification . . . ."; (3) "inventors were not in possession of administration of the compounds to patients with moderate or severe renal impairment, which is covered by the asserted claims"; and (4) "with respect to obviousness, Janssen trial testimony surprisingly revealed Janssen's position, for the first time, that the prior art did not disclose (1) the same formulation as that in Janssen's commercial product, and (2) the particle size limitations required by the asserted claims." (Def.'s Letter Br. 2-3.)

Pharmascience's position is that its application is timely and good cause has been shown because these new positions were revealed for the first-time during trial. It received the trial transcripts in January 2021, and on February 4, 2021, raised its proposed amendments. Following a meet and confer, the issue was raised with the Court shortly thereafter. Pharmascience contends it did not know of Janssen's invalidity positions prior to trial because the parties to this case had agreed to defer Janssen's response to invalidity contentions until the *Teva* trial was over. All of Pharmascience's proposed amendments are outlined with reference to the trial transcript. *See* Def.'s Letter Mot., Ex. A.

Janssen states that Pharmascience could have and should have developed its supposedly new contentions early in the case by reviewing the patent and prosecution history. It disputes that trial gave rise to any new information, and instead contends that what has really happened is that Pharmascience has changed counsel, who has come up with new theories they are attempting to slide belatedly into the case.

The parties plainly dispute what happened at the *Teva* trial and how important it really is to the invalidity positions sought to be advanced in this case. And Pharmascience does acknowledge that generally speaking Section 112 arguments could have been developed prior to trial; however, what Pharmascience contends is that the trial was the first time that it became aware of how Janssen was interpreting and supposedly limiting certain patent claims.

While Janssen disputes that characterization of the *Teva* trial testimony, the Court is not in a position to definitively decide such an embedded issue in the context of the amendment of contentions. What the Court is left with is essentially a fact dispute about the context of trial testimony and whether it supports revising contentions. What can't be disputed, however, is that Pharmascience raised the issue quickly after reviewing the trial transcripts and stands behind the references to the transcripts provided with their amended contentions as the basis to support them. To reject this showing as sufficient good cause would require the Court to adopt Janssen's position that this trial testimony does not give rise to any plausible invalidity theory, which is not possible to do on this

record. As such, the Court concludes that the concept of amending the contentions was raised in a timely fashion and that there is good cause to support the request.

**ii. Undue Prejudice**

In deciding whether Pharmascience's proposed amendments would prejudice Janssen, the decides considers whether the amendments would (1) require the opposing party to expend significant additional resources; or (2) significantly delay resolution of the dispute. *See, e.g.*, *TFH Publications v. Doskocil Mfg. Co.*, *Inc.*, 705 F. Supp. 2d 361, 366 (D.N.J. 2010). I do not see either as an issue in this case.

Despite its age, the case is not near motion practice or a trial. Indeed, there was initially movement toward an agreement to hold this case in abeyance pending the *Teva* trial. While that did not happen, fact discovery does not appear to be complete (and the parties have ongoing disputes), and expert discovery is scheduled through October 2021. The 30-month stay does not expire until May 2022. Allowing the contemplated amendments might result in a small delay of discovery, but it would not cause a "significant delay" that would materially alter when this case is reached. Moreover, no showing that the amendments would cause a dramatic increase in cost or expense has been shown.

For the reasons stated above, Defendant's letter motion to amend its invalidity contentions is **GRANTED**.

**SO ORDERED**.

**s/Mark Falk**
**MARK FALK**
**United States Magistrate Judge**

**Dated: June 24, 2021**